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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,294	11/22/2006	Debbie Stevens-Wright	B1075.71016US01	1798

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EXAMINER
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PEFFLEY, MICHAEL F

ART UNIT	PAPER NUMBER
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3739

MAIL DATE	DELIVERY MODE
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02/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,294	<b>Applicant(s)</b> STEVENS-WRIGHT, DEBBIE	
	<b>Examiner</b> Michael Peffley	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12, 14-16, 20, 23-25, 27, 29, 30, 34, 35, 38 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-10, 12, 14-16, 20, 23-25, 27, 29, 30, 38 and 44 is/are rejected.
- 7) ☐ Claim(s) 5 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/14/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

***Election/Restrictions***

Applicant's election without traverse of the invention of Group I and the species of Figure 5, to include claims 1-10, 12, 14-16, 20, 23-25, 27, 29, 30, 38 and 44, in the reply filed on September 26, 2008 is acknowledged. Claims 34 and 35 are withdrawn from consideration.

***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 12, 14-16, 20, 23-25, 27, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Rittman, III et al (6,575,969).

Rittman discloses a system that receives signals of various operating parameters and utilizes those signals to affect control of the operating parameters of the RF generator. In particular, Rittman discloses that fluid is delivered to tissue, and that flow rate, temperature and impedance signals are fed back to a controller. Figure 7 specifically shows the temperature, power and fluid flow signals provided to the

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controller (709) which then controls the output power of the RF generator (707).

Column 12, lines 30-43 specifically discloses the use of impedance measurement as a feedback signal for controlling the output of the generator. Rittman also specifically disclose real-time imaging for providing a signal to the controller to control generator outputs (col. 14). The images in real time show a display of the probe with respect to the ablation lesion being created and the size of the tumor, and thus provide a signal representing a distance from the ablation electrode to the target tissue (i.e. from the electrode tip to the tumor tissue that has not yet been ablated). Rittman teach the use of various algorithms, finite modeling and other calculations for receiving all this information, processing the information and formulating an output for the generator (col. 14, lines 10-22). The geometry of the electrode is also taken into consideration by the controller (col. 12, lines 30-40).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rittman, III et al ('969) in view of the article to Jain et al ("A Three-Dimensional Finite Element Model of Radiofrequency Ablation with Blood Flow and its Experimental Validation").

The Rittman, III et al system has been addressed previously. While Rittman discloses providing signals regarding fluid flow through the probe to control the power

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and temperature of the probe, there is no disclosure of monitoring the flow rate of blood around the probe and controlling energy based on that parameter.

Jain et al teach in the article that it is generally known that blood flow provided around a probe effects the cooling of an RF electrode, and that it is advantageous to provide a feedback signal of the blood flow around a probe in order to more accurately control the temperature of an RF probe in the body.

To have provided the Rittman system with a blood flow sensor to monitor blood flow around the probe and to more accurately control the delivery of RF energy to the probe would have been an obvious consideration for the skilled artisan in view of the teaching of Jain et al.

Claims 1, 2, 9, 10, 12, 14-16, 23-25, 30, 38 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (6,409,722) in view of the teaching of the article to Zhang et al ("Noncontact Radio-Frequency Ablation for Obtaining Deeper Lesions").

Hoey et al disclose another system that provides various feedback data to control the output of an RF ablation device. Specifically, Hoey et al disclose a flow sensor and an impedance and temperature feedback system to provide feedback to a controller to control the output parameters of the electrosurgical generator. The output power, voltage, current and the flow rate may all be controlled based on sensed conditions (Abstract). Hoey et al fail to teach providing a signal related to the distance of the

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ablation electrode from tissue as part of the feedback data used to control the energy output.

Zhang et al teach that it is generally known to vary fluid flow rates and energy from the generator based on the distance of the electrode from the tissue being treated (see Abstract). The distance was maintained using spacers to provide a desired distance from the electrode to the tissue in a non-contact ablation procedure. The user would select the desired spacing when setting the output for the generator for the procedure.

To have provided the Hoey et al system with a spacing element to provide for non-contact ablation of a target tissue would have been an obvious modification for one of ordinary skill in the art in view of the teaching of Zhang et al. To have further provided the specific spacing used as an input to the controller to control the output parameters of the system would have been an obvious consideration, particularly since Zhang et al teach that it is known to vary output parameters based on the fluid flow rate and distance of the electrode from tissue.

Claims 3, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoey et al (6,409,722) in view of the teaching of the article to Zhang et al ("Noncontact Radio-Frequency Ablation for Obtaining Deeper Lesions") and further in view of the teaching of Rittman, III et al ('969).

While it would be intuitive to use algorithms and/or finite element modeling to arrive at the specific relationships between the various feedback parameters and the

generator output of the Hoey et al system, there is no express disclosure in Hoey of using such an analysis in generating the output relationships between the generator and the feedback signals.

Rittman, as addressed previously, disclose an analogous RF ablation system that includes a controller that receives various input signals and correlates the input signals into desired output parameters for the RF generator. In particular, Rittman teach of using various algorithms, finite modeling and other relationships for correlating the output parameters of the RF generator to the input signals (col. 14, lines 10-22).

To have provided the Hoey et al system, as modified by the teaching of Zhang et al, with an algorithm or modeling program to correlate the generator output to the received feedback signals would have been an obvious modification for one of ordinary skill in the art since Rittman fairly teaches it is generally known to use such algorithms and modeling in an analogous system.

### ***Allowable Subject Matter***

Claims 5 and 6 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Eggers et al (7,422,585) and Negus et al (5,893,848) disclose other RF ablation devices that use a proximity detector to detect the distance of the electrode from a tissue (specifically, a tissue wall) and provides feedback to control the

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generator based on the proximity data and other (e.g. temperature and/or impedance) data. Rittman, III et al (6,451,015) disclose another system that provides various forms of feedback, including imaging feedback which detects the position of an electrode relative to tissue, for controlling an RF generator.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/  
Primary Examiner, Art Unit 3739

/mp/  
February 13, 2009